IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#40 Plunkett 1-10-02 CNE

In re application of:

Nielsen et al.

Serial No.: 08/319,411 Group Art Unit: 1631

Filed: October 6, 1994 Examiner: A. Marschel

For: PEPTIDE NUCLEIC ACID CONJUGATES

I, John A. Harrelson, Jr., Registration No. 42,637 certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231. On October 29, 2001

John A. Harrelson, Jr., Registration No. 42,637

Assistant Commissioner for Patents
Washington, D.C. 20231

REQUEST FOR RECONSIDERATION

This is in response to the Final Office Action mailed on August 29, 2001, in connection with the above-identified patent application.

Claims 1, 5, 8-10, 12, 13, 15, 20, 22-24, 30-33, 37, and 39-52 are pending in this application.

Claims 1, 5, 8-10, 12, 13, 15, 20, 22-24, 30-33, 37, 39-43, 45, 46, 48, and 50 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,705,333 (the 333 Patent). The 333 Patent, however, is not prior art against the instant invention. The priority application for the instant invention (U.S. Patent Application No.

08/108,591, the 591 priority application) has a U.S. filing date of November 22, 1993, over eight months before the filing date of the 333 Patent. The Office Action is mistaken with respect to its assertion that the 591 priority application only shows terminal sites for conjugates, and that the applicant is not entitled to rely on the priority disclosure to predate the 333 Patent. Page 15, lines 32-35 of the 591 priority application, for example, states that L can comprise DNA intercalator or reporter ligand. Also, Figure 1 on page 8 clearly shows L as appearing at an intermediate position from the backbone. On page 17, lines 13-27, the 591 priority application allows that conjugates can be effector ligands such as reporter ligands, water-soluble polymer, enzymes, ligands with nuclease activity, or alkylating agents. In view of this and other disclosure, Applicants maintain that the 591 priority application predates the 333 Patent, and that it is improper to apply the teachings of 333 Patent to the present invention.

The Office Action is also mistaken with respect to its apparent assertion that the constituent nucleobases of the 333 Patent's PENAM (or, presumably, of the claimed PNAs) qualify as reporters by virtue of their detectability by UV light, or as aromatic lipophilic moieties. Those skilled in the art, reading the specification, would readily understand that the constituent nucleobases of the claimed PNA structures, which serve to participate in, for example, Watson-Crick or Hoogsteen type binding, are distinct from the appended conjugate groups of the PNA. Moreover, the 591 priority application discloses reporter groups at page 17, line 16, and also discloses nucleobases at numerous places throughout the specification. Thus, even if one were to attempt to argue that the 333 Patent's PENAM nucleobases are conjugate groups according to the claims (a position with which the Applicants would disagree), such disclosure is not prior art against the present claims because the 591 priority application discloses such nucleobases.

Claims 8-10, 15, 20, 22-24, 30-33, 37, 40, 41, and 45-50 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No.5,623,049 (the 049 Patent). By reasoning analogous to that detailed above in regard to the rejection based on the 333 Patent, Applicants reinterate their argument that the 591 priority application predates the 049 Patent and, as such, the 049 Patent is improperly applied to the instant invention. The 591 priority application has a U.S. filing date of November 22, 1993, while the 049 Patent was filed September 6, 1994. Thus, Applicants' respectfully request withdrawal of this rejection.

Claims 1, 5, 8-10, 12, 13, 15, 20, 22-24, 30-33, 37, 39-43, and 45-52 are rejected under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 1-3 of U.S. Patent 5,539,082 (the 082 Patent). Although the Office Action asserts that the constituent nucleobases of the PNA of the 082 Patent qualify as cross-linkers of the present invention, this assertion is not supported by any evidence that the nucleobases would function in this manner. In the absence of such evidence, Applicants respectfully request withdrawal of this rejection. However, even if the Office Action's assertion is correct (a point Applicants do not concede), the instant invention still would not have been obvious. As is well recognized, claims cannot be found obvious in view of prior art references unless the references themselves suggest that their respective teachings should be modified in a way that would produce the claimed invention. *Berghauser v. Dann*, 204 U.S.P.Q. 393 (D.D.C. 1979); *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 221 U.S.P.Q. 929 (Fed. Cir. 1984). There must be something in the prior art that would have motivated persons of ordinary skill to make any necessary modifications. *In re Stencel*, 4 U.S.P.Q.2d 1071, 1073 (Fed. Cir. 1987), *accord*, *Ex parte Marinaccio*, 10 U.S.P.Q.2d 1719 (Pat. Off. Bd. App. 1989).

Applying the above tenets to the present situation, the 082 Patent does not teach or suggest the presently claimed subject matter. Although the Office Action asserts that the 082 Patent shows use of cross-linking agents, those skilled in the art, reading the specification, would readily understand that the constituent nucleobases of the claimed PNA structures (which serve to participate in, for example, Watson-Crick or Hoogsteen type binding) are distinct from the appended conjugate groups of the instantly claimed PNAs. Therefore, the disclosure in the 082 Patent does not render the instant invention obvious.

Claims 1, 5, 8-10, 12, 13, 15, 20, 37, 39-41, 47-49, 51, and 52 are rejected under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claim 1 of U.S. Patent 5,773,571. Claim 50 is rejected under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 1, 5, and 8 of U.S. Patent 5,786,461. Claims 8-10, 15, 20, 30-33, 37, 40, 41, 47-49, 51 and 52 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1 and 9 of U.S. Patent 5,719, 262. Claims 8-10, 15, 20, 30-33, 37, 40, 41, 47-49, 51, and 52 are provisionally rejected under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 4, 5, 9, and 40 of copending application Serial No. 08/275,951. Claims 22-24, 45, 46, and 50 are provisionally rejected under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 8, 34, 35, 37, 40-47, 49-51, 53-56, 61-63, 66-69, 71-76, and 89-93 of copending application Serial No. 08/468,719. Claims 1, 5, 8-10, 15, 20, 30-33, 37, 40, 41, 47-49, 51, and 52 are provisionally rejected under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 1, 5, and 13 of copending application Serial No. 08/686,114 (the 114 application) taken in view of PCT Patent Application 86/05518

(the Summerton reference). Claims 1, 5, 8-10, 12, 13, 15, 20, 22-24, 30-33, 37, 39-52 are provisionally rejected under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 24, 26, and 28 of copending application Serial No. 09/106,667. For reasons analogous to those discussed in the obviousness-type double patenting rejection based on the 082 Patent, there is no support for the assertion that the constituent nucleobases of the cited patents would perform as cross-linkers of the present invention. Even if this assertion were correct (a point Applicants do not concede), one skilled in the art, reading the specification, would readily understand that the constituent nucleobases of the claimed PNA structures (which serve to participate in, for example, Watson-Crick or Hoogsteen type binding) are distinct from the appended conjugate groups of the instantly claimed PNAs. As such, these rejections should be withdrawn.

Claims 1, 5, 8-10, 12, 13, 15, 20, 37, 39-41, 47-49, 51, and 52 are provisionally rejected under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 2, 6, 7, 9, 22, 24, 25, 27, 35, 37-39, and 44 of copending application Serial No. 08/275,951 (the 951 application) taken in view of Switzer et al. (Bioch. 32:10489 [1993]; the Switzer reference). The Office Action asserts that the teachings of the Switzer reference support a finding of obviousness. However, the teachings of the Switzer reference concern only the ability of various polymerases to catalyze the template-directed formation of a base pair between isoguanine and isocytosine in duplex ***oligonucleotides*** (*See* the Switzer reference Abstract, page 10489). The 591 application concerns peptide nucleic acids (PNAs). As the Switzer reference does not so much as teach or suggest the application to ***PNAs*** and the Office Action fails to provide such motivation, Applicants respectfully request reconsideration and withdrawal of the double patenting rejection based on the 951 application.

Claims 1, 5, 8-10, 12, 13, 15, 20, 37, 39-41, 47-49, 51, and 52 are provisionally rejected as obvious under the judicially created doctrine of obvious-type double patenting as allegedly being unpatentable over claims 2, 6, 7, 34, 35, 38, 40, and 42 of copending application Serial No. 08/765,798 (the 798 application) taken in view of the Switzer reference. The arguments made in regard to the rejection based on the 951 application and the Switzer reference apply equally to this rejection. As was the case with the 951 application, there was no motivation to apply the teachings of the Switzer reference to the 798 application due to the structural differences between oligonucleotides and PNAs. Thus, Applicants respectfully request withdrawal of this rejection.

Applicants submit that the foregoing constitutes a full and complete response to the Office Action and that the pending claims are in condition for ready allowance. An early office action to that effect is, therefore, earnestly solicited.

Respectfully submitted,

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